IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

AltaThera Pharmaceuticals LLC, Plaintiff, vs. Hyloris Pharmaceuticals SA, Academic Pharmaceuticals Inc., John C. Somberg, M.D., Defendants.	Civil Action No. **DEMAND FOR JURY TRIAL**

COMPLAINT

Plaintiff AltaThera Pharmaceuticals LLC ("AltaThera") brings this action for compensatory and punitive damages and permanent injunctive relief against Defendants Hyloris Pharmaceuticals SA ("Hyloris"), Academic Pharmaceuticals Inc. ("API"), and John C. Somberg, M.D. ("Dr. Somberg") (collectively, the "Defendants"), for their misappropriation of AltaThera's highly valuable trade secrets and confidential information, breaches of contract, and other tortious misconduct, in violation of both federal law under the Defend Trade Secrets Act and state law.

AltaThera also seeks a declaration that it is the owner of U.S. Patent Application No. 16/449,796 ("the '796 application"), and any patents that issue from that application (including U.S. Patent No. 11,364,213, or "the '213 patent"), as well as any patents and patent applications that claim priority to that application (including U.S. Patent Application No. 17/380,413 ("the '413 application")). AltaThera also brings this action pursuant to 35 U.S.C. § 256 to correct the inventorship of the '213 patent, to add Brandon Kashfian as a co-inventor of the subject matter claimed in that patent. AltaThera alleges as follows:

NATURE OF THE ACTION

1. AltaThera is a hospital-focused pharmaceutical company dedicated to addressing unmet medical needs, including by developing innovative ways to repurpose existing drugs and administer treatments that are efficient, safe, and effective and provide excellent outcomes for patients.

2. AltaThera is the exclusive distributor in the United States of the drug product sotalol hydrochloride injection for intravenous use ("Sotalol IV") (NDA 022306) approved by the Food and Drug Administration ("FDA") in 2009. Sotalol IV is an antiarrhythmic agent indicated for "the maintenance of normal sinus rhythm" in certain circumstances.[1] Antiarrhythmic agents such as Sotalol IV are medications that are used to treat and prevent heart rhythms that are too fast and/or irregular, *i.e.*, arrhythmias. Sotalol IV was originally approved as a substitute for oral sotalol for patients unable to take sotalol orally.

3. Consistent with AltaThera's strategic focus, the company developed an innovative method for administering Sotalol IV in a way that would allow patients who would otherwise need to spend three days in the hospital to spend only one day there. Using the method, sotalol is administered via IV for approximately one hour. After that, the patient may be switched to oral sotalol, and may be safely discharged from the hospital within one day.

4. AltaThera's work in developing and obtaining FDA approval for its new one-day dosing method for Sotalol IV required the investment of millions of dollars over several years and the development of significant, highly valuable trade secrets and confidential information

[1] Sotalol IV is a Vaughan Williams class III antiarrhythmic agent. According to its label, Sotalol IV "has both beta-adrenoreceptor blocking (Vaughan Williams Class II) and cardiac action potential duration prolongation (Vaughan Williams Class III) antiarrhythmic properties."

across a range of areas, including technological innovations, business growth strategies, physician relationship building efforts, market research, commercialization planning, and regulatory strategies.

5. Like many pharmaceutical companies, AltaThera's ability to invest the resources necessary to develop, launch, and market its innovative therapy depended on appropriate protections for the company's intellectual property, so that others could not launch and market a competing antiarrhythmic agent built on AltaThera's investments in a way that would deprive the company of an appropriate return on those investments.

6. AltaThera accordingly maintained its innovative one-day dosing method for Sotalol IV and related business and commercial strategies as confidential while it worked to prepare confidential patent applications to protect its technological innovation, materials to be confidentially submitted to the FDA in order to obtain FDA approval for this new method of use, research on the market potential for this new method, and a plan for selling Sotalol IV for use with this new method to the doctors and hospitals who could provide the drug to patients.

7. AltaThera shared its confidential information and trade secrets with Dr. Somberg—a longtime consultant purportedly acting in AltaThera's interests through Dr. Somberg's consulting company, API—and Hyloris—a publicly-traded Belgian company from which AltaThera had licensed Sotalol IV.

8. Dr. Somberg, API [redacted] entered into contracts agreeing that they would not disclose AltaThera's confidential information or use it for their own business purposes. Pursuant to these contractual guarantees, AltaThera routinely provided its highly confidential and valuable information to [redacted] in the normal course of the parties' business relationships.

9. Unbeknownst to AltaThera, [redacted] Dr. Somberg, API, and Hyloris were secretly working together to take AltaThera's novel ideas, confidential drafts and materials, market research, and know-how, and using them to bring a competing antiarrhythmic drug to market: "intravenous dofetilide" or "Dofetilide IV."

10. By the time AltaThera learned that Defendants were using its confidential information and intellectual property to pursue a competing product, Defendants were already two years into their efforts to obtain patent protection and FDA approval for a Dofetilide IV one-day dosing method. They expect to bring the product to market in 2023.

11. On information and belief, Dr. Somberg, API, and Hyloris never would have pursued Dofetilide IV at all—or, in the alternative, would not have been in a position to pursue Dofetilide IV at the times and in the ways they have—if not for their improper use of AltaThera's confidential and proprietary ideas, information, know-how, and other materials. Through AltaThera's confidential information and intellectual property, Defendants learned about the scientific and commercial potential of an antiarrhythmic drug which can be administered intravenously during a short hospital stay, resulting in savings of time and money for hospitals and patients.

12. For example, Defendants learned about AltaThera's processes which make it possible to administer antiarrhythmic drugs intravenously safely over a short time period during a one-day hospital stay.

13. Defendants also learned how this shorter hospital stay makes an antiarrhythmic drug a more attractive option for hospitals and patients, and the resulting market potential. Hyloris has admitted as much, publicly stating that, "*based on* [a] *survey performed by* ...

AltaThera … a significant portion of the existing dofetilide use in hospitals for loading of patients could be converted to IV." (emphasis added).

14. Further, following a confidential meeting AltaThera had with the FDA [redacted], Defendants learned about a cheaper, faster pathway to FDA approval and AltaThera's confidential roadmap for quickly obtaining approval using that pathway for a new method of administering an antiarrhythmic drug. Defendants also learned that the FDA would be receptive to the use of this new regulatory pathway for the approval of new formulations, methods of use, or indications for an IV antiarrhythmic agent.

15. With the benefit of AltaThera's intellectual property and confidential information, Defendants secretly began to develop Dofetilide IV. For example, Dr. Somberg copied verbatim significant portions of a highly confidential patent application he helped prepare for AltaThera into a patent application for Dofetilide IV in his own name, and in doing so failed to identify the inventive contributions of AltaThera's founder, Brandon Kashfian. On information and belief, Dr. Somberg similarly copied portions of AltaThera's confidential regulatory materials prepared in connection with AltaThera's efforts to secure FDA approval of the one-day method for administering Sotalol IV. As for Hyloris, Hyloris has publicly admitted that "[b]ased on the similarities between sotalol and dofetilide, Hyloris has adopted *a very similar development strategy* [to AltaThera's strategy for Sotalol IV] for Dofetilide IV"—a development strategy Hyloris was able to learn only through access to AltaThera's confidential information and trade secrets—and "will therefore develop Dofetilide IV and propose a new loading dose strategy *based on the same scientific rationale* [as that of the Sotalol IV one-day method] … reducing hospitalization duration."

16. AltaThera brings this action to obtain relief—including damages and injunctive relief—from Defendants' breaches of contract and tortious misconduct, and to protect AltaThera's intellectual property.

PARTIES

17. Plaintiff AltaThera is a limited liability company organized under the laws of the State of Delaware. Its principal place of business is 311 South Wacker Drive, Suite 6030, Chicago, Illinois, 60606.

18. Defendant Hyloris is a public limited liability company organized under the laws of Belgium. Its principal place of business is Boulevard Gustave Kleyer 17, 4000 Liège, Belgium.

19. Defendant API is a corporation organized under the laws of the State of New York. Its principal place of business is 21 N. Skokie Highway, Suite G3, Lake Bluff, Illinois, 60045.

20. Defendant Dr. Somberg is an individual who resides in Lake Forest, Illinois 60045. He is the President, Chief Executive Officer, and sole owner of API.

JURISDICTION AND VENUE

21. This action arises in part under the Defend Trade Secrets Act, 18 U.S.C. § 1836(b) ("DTSA"). The Court therefore has jurisdiction over Plaintiff's claims for violation of the DTSA under 28 U.S.C. § 1331; 18 U.S.C. § 1836(c). The action also arises in part under the Patent Act, and in particular under 35 U.S.C. § 256(b), which empowers federal courts to order the correction of the inventorship on a patent. The court therefore has jurisdiction over Plaintiff's claims for correction of inventorship under 28 U.S.C. §§ 1331.

22. The Court has supplemental jurisdiction over AltaThera's state-law claims pursuant to 28 U.S.C. § 1367. Those claims form part of the same case or controversy under Article III of the United States Constitution. AltaThera's state-law claims share common operative facts with its federal-law claims, and the parties are identical. Resolving AltaThera's federal and state-law claims in a single action serves the interests of judicial economy, convenience, consistency, and fairness to the parties.

23. Hyloris is subject to personal jurisdiction in this Court. Hyloris has purposefully availed itself of the laws of the United States by entering an agreement with Chicago-based AltaThera for the distribution of its Sotalol IV product, supplying AltaThera with Sotalol IV, and coordinating with AltaThera regarding AltaThera's efforts to obtain FDA approval for new indications and methods of use for Sotalol IV. Hyloris has continuous and systematic contacts with this State and acts it committed within Illinois and this District give rise to this action.

24. Hyloris has also expressly consented to personal jurisdiction in this Court. This complaint alleges a breach of [redacted] between [redacted]. In that [redacted][2]

25. In the alternative, this Court has personal jurisdiction over Hyloris because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met. First, AltaThera brings claims under federal law. Second, Hyloris, a Belgian company, is not subject to general personal jurisdiction in the courts of any U.S. state. And finally, Hyloris has sufficient minimum contacts with the United States as a whole to satisfy Due Process. Indeed, Hyloris's business model is

[2] [redacted]

built around the U.S. FDA's process for approval. Hyloris describes its "development strategy" on its website as "reformulating and repurposing approved pharmaceuticals primarily utili[zing] the 505(b)(2) regulatory pathway in the U.S. and similar pathways in other countries."[3] And Hyloris is working to commercialize its products "with [its] own small, specialist sales force in the U.S. targeting hospital-based cardiologists."[4]

26. API is subject to personal jurisdiction in this Court because API is headquartered in this District, has continuous and systematic contacts with this State, and has committed acts within Illinois and this District that give rise to this action.

27. Dr. Somberg is subject to personal jurisdiction in this Court because he is natural person who resides in this District, has continuous and systematic contacts with this State, and has committed acts within Illinois and this District that give rise to this action.

28. Venue is proper in this District against all of the Defendants pursuant to 28 U.S.C. § 1391(b)(1), because all Defendants reside in this District for venue purposes. Dr. Somberg is a natural person domiciled in this District, 35 U.S.C. § 1391(c)(1), and Hyloris and API are each subject to personal jurisdiction in this District with respect to this action, 35 U.S.C. § 1391(c)(2).

29. Venue is also proper in this District against all of the Defendants pursuant to 28 U.S.C. § 1391(b)(2), because a substantial part of the events or omissions giving rise to this action occurred in this District, including specific actions by each of Hyloris, API, and Dr. Somberg. Among other things, Dr. Somberg and API entered into relevant contracts in this District with AltaThera, a company headquartered in this District, and provided services pursuant to those contracts in this District. And Hyloris entered into relevant contracts to supply

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[3] About Us, Hyloris.com, https://hyloris.com/about-us/ (last visited Aug. 30, 2022).
[4] Our Strategy, Hyloris.com, https://hyloris.com/our-strategy/ (last visited Aug. 30, 2022).

AltaThera, a company headquartered in this District, with a medical drug and did supply the drug to AltaThera in this District.

30. To the extent Hyloris is not deemed to reside in this District for any particular claim or claims, venue is proper as to Hyloris under 28 U.S.C. § 1391(c)(3), which provides that defendants not resident in the United States may be sued in any judicial district.

BACKGROUND

31. AltaThera is a specialty pharmaceutical and precision medicine company which manufactures, markets, sells and distributes in the United States a class III antiarrhythmic drug: Sotalol IV.

32. Sotalol IV is administered for the management of atrial fibrillation—a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications—exclusively to patients in hospitals under supervision.

33. Through years of focused effort, AltaThera has developed an extensive network of doctors and hospitals that need intravenous antiarrhythmic drugs, special understanding of the needs of these doctors and hospitals and how to tailor a product and outreach to meet those needs, and an experienced full-time hospital-focused field force, consisting of sales representatives and doctorate-level (MD, PhD, PharmD) medical science liaisons who meet with physicians for scientific discussions on Sotalol IV. AltaThera has invested substantial money, time, and effort in understanding the antiarrhythmic drug market and the best way to serve that market.

34. As a company operating in the highly competitive and quickly evolving pharmaceuticals market, where being the first to obtain FDA approval and/or patent protection is often the difference between a company thriving or failing, AltaThera's business depends on

maintaining the confidentiality of its information, in particular information about new drugs or methods and the business and commercial plans supporting their development and launch. AltaThera therefore goes to great lengths to protect the confidentiality of its information, particularly from competitors or potential competitors.

35. AltaThera regularly requires those it does business with—including all employees and consultants—to enter non-disclosure and confidentiality agreements. Access to company information is restricted and provided even to AltaThera employees on a need-to-know basis. Employees and consultants are periodically reminded that all of AltaThera's information is considered confidential and proprietary. No one can access AltaThera's office without a keycard, and all AltaThera computers are required to be password protected.

EARLY DISCUSSIONS REGARDING SOTALOL IV

36. Approximately a decade ago, AltaThera was looking for a new drug product that fit the company's strategic goals. To that end, it entered into confidential discussions with Dr. Somberg and API regarding the commercialization of Sotalol IV.[5]

37. At the time, API owned assets relating to Sotalol IV, including a New Drug Application ("Sotalol IV NDA") (NDA #022306), which had been approved by the FDA on July 2, 2009.

38. In [redacted], AltaThera entered an agreement with Dr. Somberg and API (the "Term Sheet"), which provided that API would [redacted]

[5] Unless otherwise noted, this complaint treats API and Dr. Somberg—API's sole owner, CEO, President, and decision-maker—interchangeably.

[redacted][6] API agreed that it would not [redacted] and would [redacted][7]

39. Nonetheless, Dr. Somberg did [redacted] secretly engaging in discussions with a Belgian company—Hyloris—regarding [redacted].

40. When AltaThera threatened to take legal action against API based on violations of the Term Sheet, Dr. Somberg introduced AltaThera and [redacted].

41. [redacted] API transferred all existing interest in the Sotalol IV assets to Hyloris, which in turn granted AltaThera an exclusive license to those assets, including the Sotalol IV NDA.

Hyloris License Agreement

42. AltaThera entered into the Licensing, Development, and Supply Agreement ("Hyloris License Agreement") with Hyloris on December 1, 2014, and became the exclusive licensee [redacted] for [redacted][8] Hyloris agreed to supply AltaThera with Sotalol IV. And AltaThera and Hyloris agreed to cooperate in any potential reformulation of Sotalol IV and its development for new indications. Under the License Agreement, [redacted][9]

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[6] [redacted] Term Sheet (emphasis added).
[7] Term Sheet (emphasis added).
[8] Hyloris License Agreement, Recitals, Art. 1.2 [redacted].
[9] Hyloris License Agreement, Art. 10.2.

43. Because the parties would be sharing valuable confidential information in the course of their relationship, the Hyloris License Agreement imposed stringent obligations regarding [redacted].

44. Each party agreed not to [redacted] unless certain limited exceptions applied.[10]

45. They also agreed to [redacted][11]

46. [redacted] was defined broadly as [redacted][12] [redacted][13]

[10] Hyloris License Agreement, Art. 13.1.
[11] Hyloris License Agreement, Art. 13.3.
[12] Hyloris License Agreement, Art. 1.2 [redacted].
[13] Hyloris License Agreement, Art. 1.2 [redacted].

47. The parties acknowledged that there was no [redacted] [14] They also agreed that [redacted] [15]

DEVELOPMENT OF A NEW METHOD FOR DOSING

48. When AltaThera licensed the Sotalol IV assets in 2014, the FDA-approved indication for Sotalol IV called for at least three days of hospital monitoring in connection with the administration of the product. While this extended hospital stay was effective at reducing risk for patients, it made Sotalol IV a less desirable choice for doctors and patients, as long hospital stays can be expensive and uncomfortable. This limited Sotalol IV's potential, commercially and otherwise.

49. After licensing the Sotalol IV assets, AltaThera developed a novel idea to reduce the length of the required hospital stay through a new method of more rapidly initiating or escalating the sotalol dosage safely. Indeed, using AltaThera's method, Sotalol IV could be administered in approximately one hour prior to a switch to oral sotalol. AltaThera's one-day method would reduce the required hospital stay from three days to one. This innovation gave doctors and patients a new option for managing a dangerous condition in a safe, efficient way. It also increased Sotalol IV's commercial potential. AltaThera hired Dr. Somberg to assist in its efforts to develop and commercialize this method as more fully described herein.

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[14] Hyloris License Agreement, Art. 13.4.
[15] Hyloris License Agreement, Art. 13.4.

50. AltaThera's one-day method was originally conceived by AltaThera's founder, Brandon Kashfian.

51. The value of the technical innovation of AltaThera's one-day method was reinforced by highly valuable AltaThera confidential and trade secret information regarding, among other things, the commercial value of the innovation, the strategy for deploying the innovation in the marketplace, and the regulatory and intellectual property strategy supporting that commercial strategy. For example, AltaThera recognized, but did not disclose to the public, an opportunity to seek patent protection for its technical innovation and FDA approval for a new indication for Sotalol IV based on that innovation, which would ensure that AltaThera would have a competitive advantage in the market for IV antiarrhythmic agents over others without access to AltaThera's confidential and proprietary information.

52. AltaThera did not disclose its ideas to others who could derive economic value from them, and closely guarded its technical innovations in connection with the one-day method as valuable company trade secrets until AltaThera was granted a public patent describing its one-day method in December 2019. Much of AltaThera's related information—for example, its strategy for deploying the innovation in the marketplace—remains confidential.

53. AltaThera did disclose the technical innovations to Dr. Somberg, however. Based on Dr. Somberg's background and experience with Sotalol IV, AltaThera had retained him as an advisor and consultant via his consulting business, API, and Mr. Kashfian and Dr. Somberg worked together to refine AltaThera's novel one-day method and ultimately reduce the idea to practice.

54. In view of the critical importance of Sotalol IV to AltaThera and the value of AltaThera's trade secrets and confidential information, AltaThera was careful to protect its rights

in connection with its relationship with Dr. Somberg and API throughout the parties' relationship.

Dr. Somberg and API Confidentiality Agreement

55. In April 2016, AltaThera, Dr. Somberg, and API agreed to a Confidentiality and Non-Disclosure Agreement ("2016 API Confidentiality Agreement").[16]

56. The parties acknowledged that they would disclose confidential information to each other in the course of their relationship, and recognized that "such Confidential Information … has been developed or obtained … by the investment of significant time, effort, and expense, and that such Confidential Information provides the Disclosing Party with a significant competitive advantage in its business."[17]

57. The parties agreed that "[n]either party shall use, or allow any third party to use, any confidential information obtained from the other party for any purpose, whether business, commercial, or otherwise, unless agreed upon in writing by the parties."[18]

58. The parties would "not copy, alter, modify, disassemble, reverse engineer, or decompile any materials received from [the other party] without prior written consent" and would "return … or destroy Confidential Information or any materials prepared by [the receiving party] that incorporate any Confidential Information, promptly upon the request of Disclosing Party or after the purpose for which they were furnished or made ha[s] been accomplished or abandoned."[19]

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[16] The 2016 API Confidentiality Agreement is nearly identical to another Confidentiality and Non-Disclosure Agreement among AltaThera, Somberg, and API executed in 2011 (the "2011 API Confidentiality Agreement," together with the 2016 API Confidentiality Agreement, the "API Confidentiality Agreements").
[17] API Confidentiality Agreements, p. 2, § 1.
[18] API Confidentiality Agreements, p. 2, § 3.
[19] API Confidentiality Agreements, p. 3, § 5.

59. Each party "represent[ed] that it ha[d] not and w[ould] not in the future (except as provided in this Agreement), provide[] or communicate any of [the other party's] Confidential information to any third party."[20] Instead, the parties would "hold in confidence and [agree] not to disclose or reveal Confidential Information received hereunder to any person except for [the receiving party's] employees, directors, counsel, and advisors (collectively 'Representatives') who are required to have such Confidential Information in order to perform their functions in connection with the limited purposes of this Agreement."[21] And "[e]ach permitted Representative to whom Confidential Information is disclosed shall adhere to all aspects of this Agreement."[22]

60. The agreement defines "Confidential Information" broadly, as "any information or material which [the receiving party] may obtain knowledge of through or as a result of the relationship established hereunder with the Disclosing Party, access to Disclosing Party's premises, or communications with the Disclosing Party's employees or independent contractors."[23] It includes, without limitation, "designs, concepts, drawings, ideas, inventions, specifications, techniques, discoveries, models, data, content material, sources, documentation, diagrams, flow charts, research, development, manufacturing processes and sources, procedures, know-how, new product or new technology information, marketing techniques and materials, marketing plans, timetables, strategies and development plans, and any other information related to the discovery, manufacture, production, development, and marketing."[24]

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[20] API Confidentiality Agreements, p. 3, § 6.
[21] API Confidentiality Agreements, p. 2, § 2.
[22] API Confidentiality Agreements, p. 2, § 2.
[23] API Confidentiality Agreements, p. 1, § 2 ("Confidential Information").
[24] API Confidentiality Agreements, p. 1–2.

61. The definition is subject to limited exceptions, including for information that later becomes generally known to the public other than as a result of a breach of the agreement.

Consultant Agreements

62. AltaThera and API also executed a Consultant Agreement on January 8, 2018, and Amended and Restated Consultant Agreements on June 1, 2018 and August 22, 2019 (the "Consultant Agreements"). Through these agreements, AltaThera engaged API "to provide medical affairs, regulatory affairs, clinical affairs, and business expertise" related to Sotalol IV.[25]

63. Again, the agreements contained broad protections regarding the use or disclosure of AltaThera's information.

64. The Consultant Agreements treat *all* information pertaining to the affairs of AltaThera as confidential. API "recognize[d] and acknowledge[d] that *all information* pertaining to the affairs, business, clients, customers or other relationships of [AltaThera], as hereinafter defined, *is confidential* and is *a unique and valuable asset* of [AltaThera]."[26] And "[a]ll records, memoranda, etc. relating to the business of [AltaThera] whether made by [API] or otherwise coming into [its] possession are confidential and will remain the property of [AltaThera]."[27]

65. API agreed that it would "not make use of this type of information for [its] own purposes or for the benefit of any person or organization other than [AltaThera]."[28] API would "not at any time use or exploit any of the confidential information of [AltaThera] for any purpose other than for the benefit of [AltaThera]."[29] Thus, for example, Dr. Somberg and API agreed that any work "relating to" AltaThera's business, even if "made by" Dr. Somberg, was *AltaThera's*

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[25] Consultant Agreements, Preamble.
[26] Consultant Agreements, § VI.B (emphases added).
[27] Consultant Agreements, § VI.B.
[28] Consultant Agreements, § VI.B.
[29] Consultant Agreements, § VI.E.

confidential information, and the property of AltaThera, which Dr. Somberg and API could not use for *any purpose* other than for the benefit of AltaThera.

66. API also agreed that it would not "give to any person, firm, association, corporation or governmental agency any information concerning the affairs, business, clients, customers or other relationships of [AltaThera] except as required by law."[30] Further, API would "use reasonable efforts to prevent the disclosure of this information by others."[31]

67. The Consultant Agreements were also clear that anything API developed as a result of, or relating to, its services during its engagement with AltaThera would belong to AltaThera:

> The results and proceeds of [API's] services [under the Consultant Agreements], including, without limitation, any works of authorship resulting from or relating to [AltaThera's] business and/or [API's] services during [its] engagement with [AltaThera] and/or any of [AltaThera's] affiliates and any works in progress, will be works-made-for hire and [AltaThera] will be deemed the sole owner throughout the universe of any and all rights of whatsoever nature therein, whether or not now or hereafter known, existing, contemplated, recognized or developed, with the right to use the same in perpetuity in any manner [AltaThera] determines in its sole discretion without any further payment to [API] whatsoever.
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> If, for any reason, any of such results and proceeds will not legally be a work-for-hire and/or there are any rights which do not accrue to [AltaThera] under the preceding sentence, then [API] hereby irrevocably assigns and agrees to assign any and all of [its] right, title and interest thereto, including, without limitation, any and all copyrights, patents, trade secrets, trademarks and/or other rights of whatsoever nature therein, whether or not now or hereafter known, existing, contemplated, recognized or developed, to [AltaThera], and [AltaThera] will have the right to use the same in perpetuity throughout the universe in any manner [AltaThera] determines without any further payment to [API] whatsoever.
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> [API] will, from time to time, as may be requested by [AltaThera], do any and all things which [AltaThera] may reasonably deem useful or desirable to establish or document [AltaThera's] exclusive ownership of any and all rights in any such results and proceeds, including, without limitation, the execution of appropriate copyright and/or patent applications or assignments. To the extent [API has any rights in the results and proceeds

[30] Consultant Agreements, § VI.B.
[31] Consultant Agreements, § VI.B.

> of his/her services that cannot be assigned in the manner described above, [API] unconditionally and irrevocably waives the enforcement of such rights.[32]

68. Further, API agreed that it would, "with reasonable notice during or after the Period of Engagement, furnish information as may be in his/her possession and cooperate with [AltaThera] as may reasonably be requested in connection with any … legal actions in which [AltaThera] is or may become a party."[33]

69. API acknowledged that its "breach or threatened or attempted breach" of any of these provisions "would cause irreparable harm to [AltaThera] not compensable in monetary damages and that [AltaThera] shall be entitled, in addition to all other applicable remedies, to a temporary and permanent injunction and a decree for specific performance … without being required to prove damages or furnish any bond or other security."[34]

Regulatory Efforts

70. From 2017 through 2020, AltaThera, relying heavily on Dr. Somberg in his role as a paid advisor and consultant, took concrete steps to obtain FDA approval for its Sotalol IV one-day method of use, and to make the one-day method available to doctors and patients.

71. In order to obtain FDA approval for its Sotalol IV one-day method of use, AltaThera developed confidential plans to conduct a new clinical study. In order to conduct such a study, AltaThera reopened the Investigational New Drug Application ("IND") for Sotalol IV in 2017,[35] and requested feedback from the FDA on that plan.

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[32] Consultant Agreements, § VI.D.
[33] Consultant Agreements, § VI.A.
[34] Consultant Agreements, § VI.F.
[35] The IND had been placed on inactive status in 2013, following Sotalol IV's FDA approval in 2009 for use as a substitute in patients who are unable to take sotalol orally.

72. Dr. Somberg was a key member of the team preparing AltaThera's request to the FDA, and was aware of AltaThera's confidential business and strategic plans supporting that request. But the public—including anyone who could derive economic value from those plans—was not. The information disclosed to the FDA relating to the IND and the one-day method remained confidential from competitors and the public. The FDA is required by regulation to maintain the confidentiality of information submitted pursuant to an IND. 21 C.F.R. § 601.50.

73. AltaThera had a confidential meeting with the FDA [redacted]. Dr. Somberg attended on behalf of AltaThera. At that meeting, [redacted] AltaThera's strategic choice to pursue [redacted]

74. Dr. Somberg was not and would not at that time have become aware of the [redacted], but for his access to and participations in AltaThera's confidential discussions with the FDA.

75. During the [redacted] meeting and confidential follow-ups with the FDA, AltaThera (and Dr. Somberg) learned [redacted]. With significant effort, including effort undertaken by Dr. Somberg and API on AltaThera's behalf, AltaThera developed a confidential plan for obtaining approval through the MIDD Pilot Program, and prepared a confidential MIDD meeting package and related material for FDA review, which it submitted to the FDA in [redacted] in order to obtain approval of its new indication. After considerable effort and numerous interactions with the FDA, AltaThera was the first company accepted into the FDA's MIDD Pilot Program. AltaThera's plan for navigating the MIDD Pilot Program, and its MIDD meeting package and related material, were the first of their kind under this FDA program. AltaThera's confidential plans and FDA regulatory submission materials reflected significant investments and gave AltaThera a unique competitive advantage in connection with any similar future plans and submissions, particularly in connection with similar intravenous antiarrhythmic agents.

76. Dr. Somberg, acting on AltaThera's behalf, played a key role in developing AltaThera's plan, MIDD meeting package, and related material.

77. AltaThera did not disclose its plan or MIDD meeting package to the public, and the FDA was required to retain the confidentiality of its discussions with AltaThera and AltaThera's MIDD meeting package.[36]

78. AltaThera filed a supplemental NDA to broaden the use of Sotalol IV to encompass AltaThera's one-day method, with assistance from Dr. Somberg, on May 6, 2019. The information in the supplemental NDA remained confidential. The FDA is prohibited by regulation from publicly disclosing the existence of pending NDAs. 21 C.F.R. § 314.430.

79. The FDA approved the Sotalol IV one-day method in March 2020.

Patent Protection

80. AltaThera also sought patent protection for its novel method.

81. In 2018, AltaThera asked Dr. Somberg to draft significant portions of a patent application, including an invention disclosure and claims, specifically directed to AltaThera's one-day method, that would be used in connection with the filing of a patent application with the USPTO ("Sotalol IV Patent Application").

82. AltaThera urged Dr. Somberg to act quickly in preparing these disclosures to support the Sotalol IV Patent Application, with a goal of filing "well before" the FDA meeting [redacted]. But Dr. Somberg did not send AltaThera a first draft of significant portions of the Sotalol IV Patent Application until well after the FDA meeting, on June 14, 2018.

83. On August 14, 2018, AltaThera filed the Sotalol IV Patent Application as U.S. Patent Application No. 16/103,815, entitled "Method of initiating and escalating sotalol hydrochloride dosing." The patent application reflects the joint inventive efforts of Dr. Somberg

[36] MIDD Pilot Program Frequently Asked Questions, FDA, https://www.fda.gov/drugs/development-resources/midd-pilot-program-frequently-asked-questions (last visited Aug. 30, 2022).

and Mr. Kashfian, each of whom is listed as an inventor. The application was filed using the USPTO's Prioritized Patent Examination Program ("Track One"), which provides for a final disposition on the application "within about twelve months."

84. U.S. Patent Application No. 16/103,815 was a "result[] and proceed[] of [API's] services" under the Consultant Agreements, and therefore belonged to AltaThera. In connection with the filing of the Sotalol IV Patent Application, Dr. Somberg executed a formal, recordable assignment agreement reflecting the already-operative assignment of rights to intellectual property contemplated by the terms of his Consulting Agreements, memorializing that Dr. Somberg had assigned any and all inventions described in the patent application to AltaThera.

85. Additionally, Dr. Somberg executed a Declaration pursuant to 37 C.F.R. § 1.63 in which he declared, under penalty of perjury, that he had authorized the filing of the Sotalol IV Patent Application—naming him, Mr. Kashfian, and Dr. Janus Molnar as joint inventors—and that he believed he was the original inventor or, as applicable here, an original joint inventor of an invention claimed in the application.

86. Federal law generally requires the USPTO to keep patent applications "in confidence" for eighteen months after filing. 35 U.S.C. § 122. Because AltaThera's application was allowed in less than eighteen months, however, it was published when the patent issued on December 24, 2019 as U.S. Patent No. 10,512,620.

Market Research and Know-How

87. AltaThera conducted extensive, confidential market research that demonstrated that there was a valuable opportunity in the U.S. market for Sotalol IV administered using AltaThera's one-day method. This proprietary information led AltaThera to pursue its new method.

88. AltaThera also developed a confidential strategy and know-how for launching Sotalol IV for its new indication into this new market. As part of its efforts, AltaThera hired personnel with relevant expertise who invested substantial time working on AltaThera's behalf to refine the company's strategy. It collected data on [redacted]. AltaThera researched and created business strategies based on the [redacted]—all of which would be required for the successful adoption of the new one-day dosing regimen for Sotalol IV.

89. AltaThera closely guarded the confidentiality of its market research, strategy, and know-how and did not disclose it outside the company, except to those who were bound to maintain its confidentiality.

Disclosures to Hyloris

90. From the beginning of their relationship (as governed by the Hyloris License Agreement executed in 2014),[37] AltaThera [redacted].

[37] *Supra* ¶ 42.

91. As AltaThera was approaching the commercial launch of Sotalol IV for the new market that could be reached with its one-day method, AltaThera and [redacted]

92. The [redacted] states that [redacted][38]

93. The [redacted][39] [redacted][40]

94. Hyloris also [redacted]

38 [redacted]
39 [redacted]
40 [redacted]

[redacted][41]

95. Hyloris also [redacted][42]

96. Hyloris also [redacted][43]

97. The [redacted]

41 [redacted]
42
43

[redacted][44]

98. [redacted] also explicitly includes [redacted]

[redacted][45]

99. There are [redacted]

100. [redacted]

[redacted][46] Hyloris therefore [redacted]

[redacted][47]

101. In phone calls held approximately weekly, as well as in emails and in person, AltaThera—pursuant to [redacted]

---

44 [redacted]
45
46
47

[redacted]

102. In light of Hyloris's [redacted] and the parties' business relationship, AltaThera [redacted] in reliance on the reasonable expectation that Hyloris would protect AltaThera's confidential information and would not improperly use or disclose that information outside the parties' relationship—and certainly not to develop a competing antiarrhythmic agent.

DEFENDANTS' IMPROPER USE AND DISCLOSURE OF ALTATHERA'S CONFIDENTIAL INFORMATION

103. From 2017 through the FDA's approval of Sotalol IV for the new method in March 2020, AltaThera believed that Dr. Somberg, API, and [redacted] were in compliance with their [redacted] to protect AltaThera's confidential information, using such information only for AltaThera's benefit[redacted]. AltaThera later learned that this was not the case, however. Instead, Dr. Somberg, API, and Hyloris were improperly using and disclosing AltaThera's confidential and proprietary information to enrich themselves at AltaThera's expense—and ultimately planning to use that confidential and proprietary information to develop and launch a competing intravenous antiarrhythmic agent.

104. While receiving fees from AltaThera and purportedly working on its behalf, Dr. Somberg and API were taking the confidential ideas, information, know-how, and work product that they got from AltaThera or that otherwise resulted from their relationship with AltaThera—including AltaThera's method for modifying product dosing to shorten a hospital stay from three days to one day—and copying and otherwise using them to make the same one-day dosing

method AltaThera developed for Sotalol IV available for a product that directly competes with Sotalol IV: another class III antiarrhythmic drug, intravenous dofetilide, i.e., Dofetilide IV.

105. In April 2019—after the critical [redacted] FDA meeting, and well before any information about AltaThera's one-day method became public—API signed a binding term sheet agreeing to license its Dofetilide IV intellectual property to Hyloris, which plans to distribute the competing product, Dofetilide IV, in the United States using its own sales force beginning in 2023. API agreed to grant Hyloris an exclusive, worldwide license to import, develop, label, use, sell, distribute, and commercialize Dofetilide IV. Hyloris agreed to reimburse API for development costs and pay API more than half a million dollars. API "will continue to support the development" of Dofetilide IV.

106. The intellectual property that Dr. Somberg and API licensed to Hyloris in connection with Dofetilide IV reflected, incorporated, and/or constituted "results and proceeds" of API's services to AltaThera under the Consultant Agreements, and therefore that intellectual property was and is owned by AltaThera, not Dr. Somberg or API.

107. On information and belief, Hyloris's decision to partner with and/or license from Dr. Somberg and API in connection with Dofetilide IV was informed by and based on the improper use—by Hyloris, Dr. Somberg, and API—of AltaThera's confidential information.

108. Hyloris described and disclosed the term sheet and terms in a prospectus relating to an initial public offering ("Hyloris IPO Prospectus") on June 17, 2020. The purpose of the Hyloris IPO Prospectus was to provide information to potential investors among the interested public, so that such investors might purchase shares of Hyloris and thereby raise capital for the company. The prospectus provided significant details regarding Hyloris's plans for Dofetilide IV because the product was an advanced drug candidate in the company's portfolio, and one falling

within the scope of Hyloris's "particular focus" on "IV cardiovascular products." Hyloris's disclosures relating to Dofetilide IV were material to potential investors' decisions to purchase shares of the company in the IPO. And on June 26, 2020, Hyloris reported that the IPO was successful: the company raised approximately €61.81 million, or almost $70 million at then-prevailing exchange rates, in material part based on the perceived strength of Hyloris's business strategy and plans for Dofetilide IV.

109. Upon becoming aware of the Hyloris IPO Prospectus, AltaThera [redacted]

110. Hyloris nonetheless has continued to promote Dofetilide IV as its product and to raise capital based on its purported rights to Dofetilide IV.[48]

111. On information and belief, Dr. Somberg and Hyloris wanted to capitalize on AltaThera's efforts without including AltaThera in any profits. So they sought out a competing class III antiarrhythmic drug which could be administered using the same one-day method: dofetilide. The FDA had approved dofetilide to be administered orally in 1999. But dofetilide had never been approved for intravenous use in the United States. The market for an intravenous antiarrhythmic drug that does not offer a dosing advantage compared to oral administration was small. Most patients could take medication orally. And sotalol was available intravenously for patients who could not. But AltaThera had now shown that intravenous administration could be *better* for hospitals and patients than oral administration, because it could be administered in a

[48] *See, e.g.*, Corporate Presentation, May 9, 2022, available through "Investors" page on Hyloris's website, at 20, https://hyloris.com/wp-content/uploads/2022/05/Corporate-Presentation-May-9-2022.pdf (describing Dofetilide IV as a "core asset").

way that made a shorter hospital stay possible. Intravenous antiarrhythmic drugs administered in this way could therefore compete with orally administered antiarrhythmic drugs. In other words, AltaThera's efforts showed that there was a market for Dofetilide IV, particularly if it was administered using AltaThera's one-day dosing method.

112. Shortly after AltaThera's [redacted] meeting with the FDA, Dr. Somberg began working to do the same thing with dofetilide that AltaThera had been working to do—and ultimately would succeed in doing—with sotalol. And he used AltaThera's confidential information and intellectual property to do so.

113. For example, while preparing the confidential patent application relating to Sotalol IV on AltaThera's behalf, and at AltaThera's expense, Dr. Somberg was copying the work he was doing for AltaThera (which constituted "results and proceeds" of API's work for AltaThera under the Consulting Agreements, and which, like the Sotalol IV Patent Application, reflected the inventive contributions of Mr. Kashfian) into a patent application relating to Dofetilide IV. Instead of working quickly on the Sotalol IV Patent Application, as AltaThera asked, Dr. Somberg delayed AltaThera's progress while converting AltaThera's ideas and intellectual property into a provisional patent application relating to Dofetilide IV ("Dofetilide IV Provisional Patent Application").

114. The Dofetilide IV Provisional Patent Application (Application No. 62/689,442) is dated, in its header, June 12, 2018. The first draft of the Sotalol IV Patent Application, which Dr. Somberg prepared for and provided to AltaThera, [redacted].

115. The Dofetilide IV Provisional Patent Application closely tracks the substance of the first draft of the Sotalol IV Patent Application that Dr. Somberg prepared for AltaThera. For

example, Dr. Somberg titled the Dofetilide IV Provisional Patent Application "A method of initiating or escalating dofetilide dose in hospital maximizing patient safety while shortening the time period required for electrocardiographic monitoring"—a near verbatim copy of the title of the confidential draft of the Sotalol IV application he was preparing for AltaThera: [redacted] (differences underlined).

116. Beyond the title, the Dofetilide IV Provisional Patent Application copies large swaths of the confidential first draft of the Sotalol IV Patent Application verbatim, including the central idea:

[redacted]

Dofetilide IV Provisional Application (differences from Sotalol IV First Draft of Application underlined):

FDA has mandated in hospital QTc monitoring in initial dofetilide loading, or for dose escalation. Telemetry monitoring is both expensive and time consuming for patients, physicians and health care professionals. Because it takes at least 3 days for dofetilide to reach a steady state concentration and thus for the concentration to be reflected in full expression in QTc prolongation. Patients may leave the hospital early endangering themselves to possible arrhythmias occurring outside the hospital where help is often not available. For reasons of safety, cost and

> convenience one can readily see that it would be useful to obtain initial dose loading or dose escalation, achieving serum dofetilide concentrations that reach the maximal peak levels seen with daily dosing in the shortest period of time, thus reducing the time needed for in hospital monitoring. If Cmax ss - the maximal concentration obtained at steady state can be achieved in less than 24 hrs., the maximum QTc will be obtained in the 24 hr. period and thus risk assessed in one day or less reducing cost, increasing compliance, as well as enhancing patient safety.
>
> One day loading with dofetilide is indeed possible.

117. Dr. Somberg hurried to file the Dofetilide IV Provisional Patent Application on June 25, 2018, well before the Sotalol IV Patent Application was filed on behalf of AltaThera on August 14, 2018.

118. Then, on June 24, 2019—six months prior to issuance and publication of AltaThera's Sotalol IV patent or patent application—Dr. Somberg and API filed the non-provisional Dofetilide IV Patent Application, claiming priority to the June 25, 2018, filing date of the provisional.

119. Again, Dr. Somberg and API copied large swaths of the still-confidential, filed version of the Sotalol IV Patent Application. For example, he titled the non-provisional Dofetilide IV Patent Application "Method of initiating or escalating dofetilide dose and formulations therefor"—a near verbatim copy of the title of AltaThera's filed application: "Method of initiating and escalating sotalol hydrochloride dosing." (Differences underlined). Upon information and belief, Dr. Somberg relied heavily on AltaThera's unpublished Sotalol IV Patent Application as a basis for the non-provisional Dofetilide IV Patent Application.

120. Dr. Somberg did not execute a formal, recordable assignment agreement relating to the Dofetilide IV Patent Applications—as he did with the Sotalol IV Patent Application—reflecting the already-operative assignment of rights in intellectual property to AltaThera pursuant to his Consulting Agreements. Instead, Dr. Somberg initially identified API as the

assignee of the inventions claimed in the Dofetilide IV Patent Applications, and he worked with Hyloris (without informing AltaThera) to allow Hyloris to use the Dofetilide IV intellectual property that, under the Consultant Agreements, belonged to AltaThera.

121. On information and belief, Dr. Somberg and API similarly used and/or copied other confidential AltaThera materials in pursuit of Dofetilide IV—acting at times in concert with Hyloris—including AltaThera's plan for obtaining approval through the MIDD program, its MIDD meeting package ([redacted]), and other AltaThera strategy documents and materials.

122. Indeed, the Hyloris IPO Prospectus discussed API's efforts relating to Dofetilide IV. In addition to obtaining the patent, API "undertook, among other things, to manage (pre-) clinical studies, perform data analysis, write product labels and provide assistance with the preparation of all required FDA applications and submissions"—the same things API had done for AltaThera relating to Sotalol IV.

123. AltaThera terminated its consultant relationship with API in 2020 upon discovering Dr. Somberg's and API's breaches of their agreements. Nearly two years later, AltaThera requested that Dr. Somberg and API provide certain of AltaThera's records, reports, and documents—each of which belonged to AltaThera under the terms of the Consultant Agreements—that were responsive and necessary to respond to an FDA request made as part of a routine FDA investigation. Rather than provide the documents as the Consultant Agreements require, API and Dr. Somberg withheld the documents in an effort to coerce AltaThera to release the claims it has against API, Dr. Somberg, and Hyloris. API hired an attorney to tell AltaThera that API would not provide the documents unless AltaThera agreed to release API and Dr.

Somberg "from any and all claims of breach of the prior agreements between API and AltaThera," recognize API's and Dr. Somberg's ownership of Dofetilide IV, and release Hyloris from claims relating to Dofetilide IV. API and Dr. Somberg still have not provided AltaThera's documents.

124. On information and belief, Hyloris knew about Dr. Somberg's and API's clandestine efforts relating to Dofetilide IV but did not notify AltaThera and instead contracted with API to receive the benefits of Dr. Somberg's and API's misappropriation and misuse of AltaThera's intellectual property and confidential information. On information and belief, Hyloris expected to benefit from Dr. Somberg's and API's misuse and misappropriation, because it understood that they would license their rights in Dofetilide IV to Hyloris, and that, by misappropriating AltaThera's trade secrets and confidential information, Hyloris could potentially profit substantially from Dofetilide IV, without having to share those profits with AltaThera.

125. Hyloris's investment in and development of a competitive intravenous antiarrhythmic agent to Sotalol IV could lead to reduced Hyloris licensing revenues from AltaThera on Sotalol IV, but Hyloris was motivated to undercut Sotalol IV for several reasons. First, as Hyloris explained in its IPO Prospectus, it expects the sale price of Dofetilide IV "to be higher than Sotalol IV," because the application of AltaThera's method to Dofetilide IV will shorten hospital stays even more and thus result in "greater value added to the healthcare system."[49] And, second, Hyloris can cut AltaThera out of the equation when it comes to Dofetilide IV and therefore pocket a greater percentage of profits. So, although Hyloris benefits

[49] A company issuing an IPO prospectus must only make claims it believes to be accurate, as "deceptive" representations violate the Securities Exchange Act, 15 U.S.C. § 78j(b).

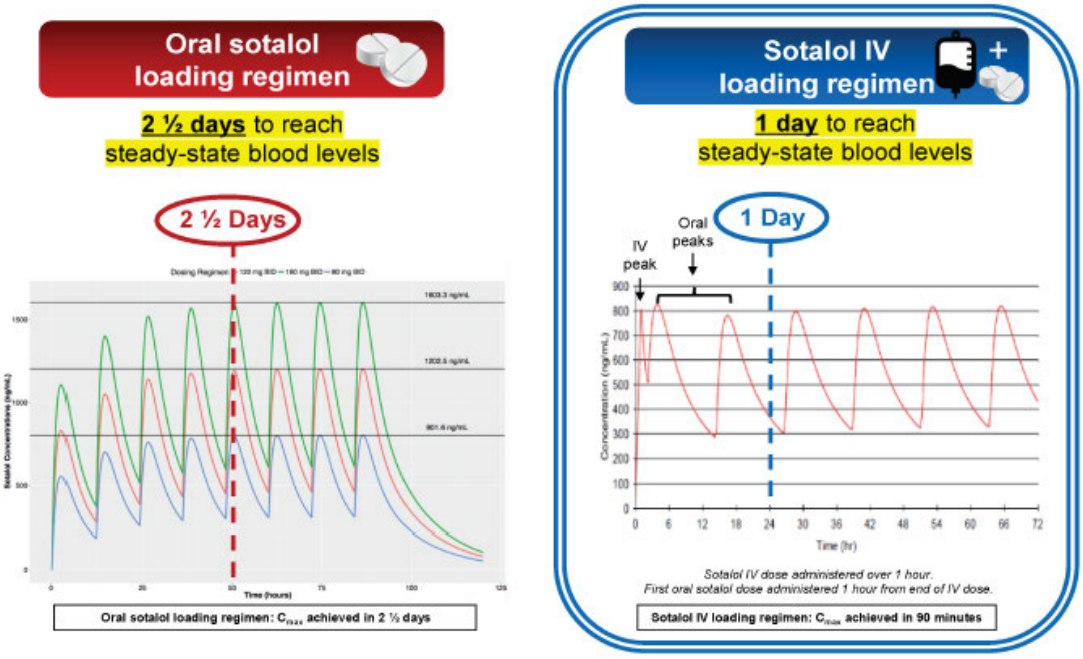
from sales of Sotalol IV under the Hyloris License Agreement, Hyloris expects to benefit more from sales of Dofetilide IV.

126. In an effort to realize these gains, Hyloris itself was misusing and misappropriating AltaThera's intellectual property and trade secrets.

127. For one thing, Hyloris relied on confidential data developed by AltaThera in deciding to acquire Dofetilide IV and in developing its plan to commercialize it. As Hyloris stated in its IPO Prospectus, "Based on the similarities between sotalol and dofetilide, Hyloris has adopted *a very similar development strategy* [to AltaThera's strategy for Sotalol IV] for Dofetilide IV, which is currently only available as an oral capsule. Hyloris will therefore develop Dofetilide IV and propose a new loading dose strategy *based on the same scientific rationale* [as that of the Sotalol IV one-day method] with a faster loading followed by oral therapy. As a result, patients should reach steady state of dofetilide faster, reducing hospitalization duration."

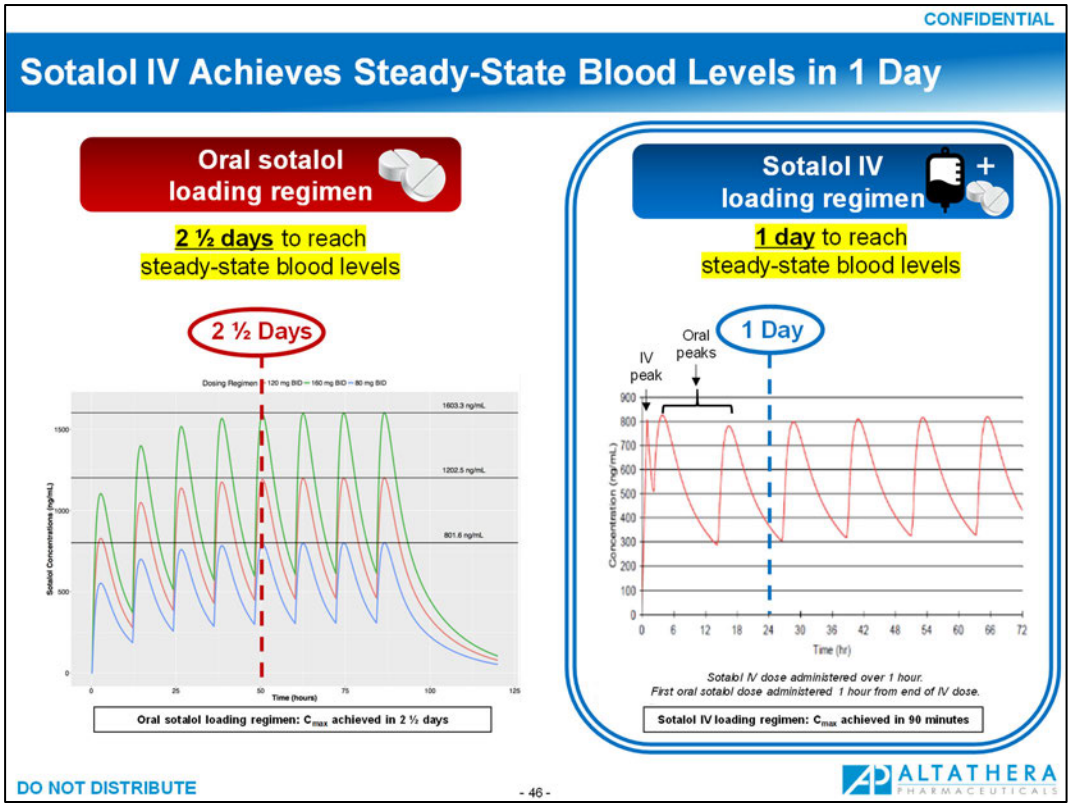
128. In addition to relying on AltaThera's information to create its own (competing) business plans, Hyloris both used and disclosed AltaThera's confidential data in the IPO Prospectus.

129. For example, Hyloris copied and pasted a slide directly from a confidential AltaThera presentation (even noting that the source of the graphic was "AltaThera").



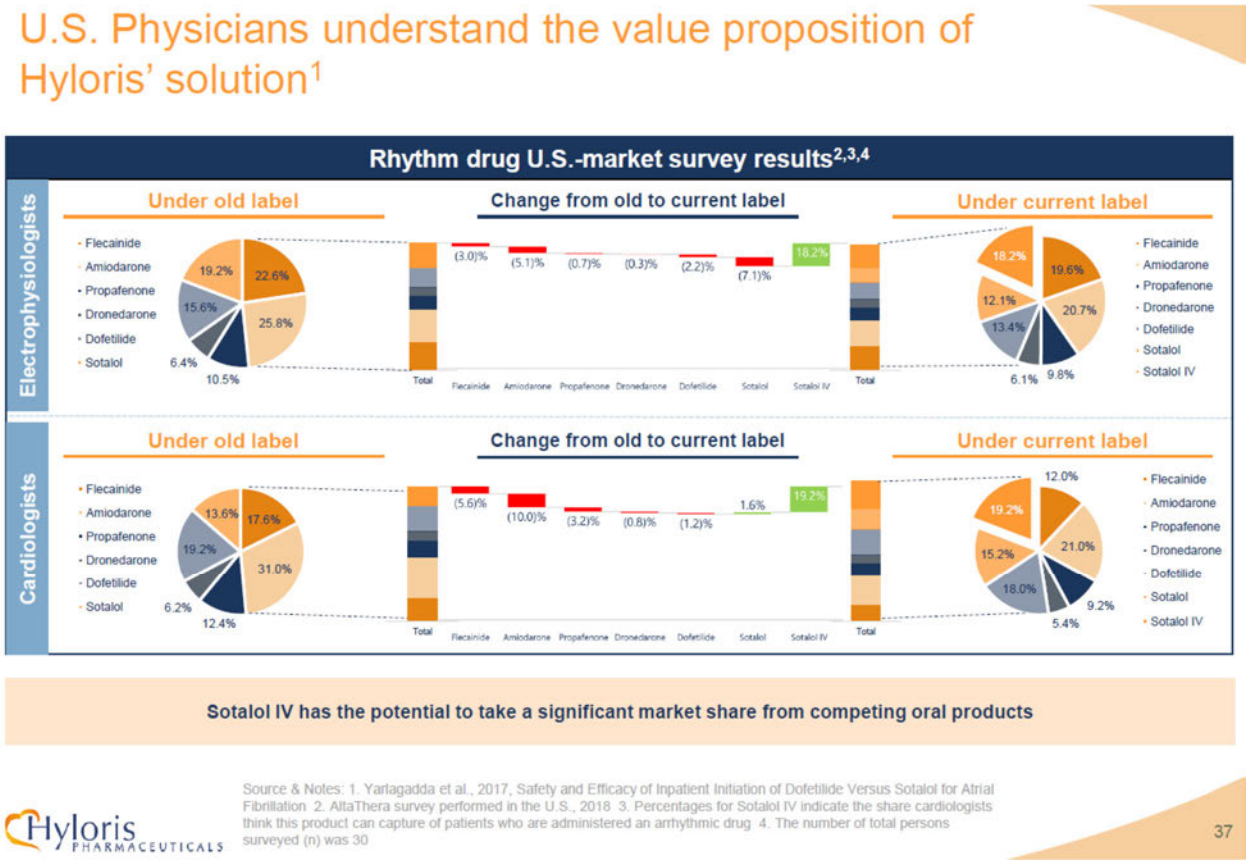
Source: AltaThera

130. When AltaThera provided this graphic to Hyloris, it was marked "CONFIDENTIAL" and "DO NOT DISTRIBUTE" as shown below.



131. The IPO Prospectus also made extensive disclosures about AltaThera's market research, which Hyloris admittedly used for its own business purposes. Hyloris disclosed that, "*based on* the Sotalol IV numbers of *the survey performed by … AltaThera* … a significant portion of the existing dofetilide use in hospitals for loading of patients could be converted to IV." (emphasis added). Hyloris was aware that the sales potential of Sotalol IV is based on converting a portion of existing oral sotalol use *and* a portion of oral dofetilide use in hospitals.

132. Hyloris further disclosed the details of AltaThera's market research, explaining that, in 2018, "AltaThera conducted a survey of 30 electrophysiologists and cardiologists in order to assess the adult AFib opportunity for Sotalol IV in the United States." Hyloris even included a diagram revealing the results of AltaThera's proprietary study, noting that its source was an "AltaThera survey."



133. Hyloris also [redacted] by publicly disclosing in its IPO Prospectus (1) the sale price of Sotalol IV, which was not public prior to publication of Hyloris's IPO Prospectus, (2) AltaThera's confidential sales data, including both current sales and future sales estimates, and (3) details regarding the terms of the License Agreement.

134. For example, the Hyloris IPO Prospectus stated that "current sales of Sotalol IV, which was made available in the United States in 2015, are therefore very limited (USD 2.1 million in 2019 with a drug price that was above USD 2,000 per vial at the end of 2019)." [redacted] AltaThera did not begin reporting its wholesale acquisition cost to publicly available drug pricing compendia until after Hyloris publicly disclosed it.

135. The Hyloris IPO Prospectus also disclosed in detail the confidential terms of the Hyloris License Agreement, including, for example, that under that agreement "Hyloris will receive sales related royalties ranging from a high single digit percentage to a low double digit percentage as well as up to five one-time (increasing) milestone payments, that become payable when defined aggregate sales targets are exceeded, with a maximum total aggregate of USD 18 million."

136. Further, for the first time, Hyloris is developing, and plans to use, its own sales force for the distribution of Dofetilide IV in the United States. On information and belief, Hyloris has used AltaThera's confidential information and intellectual property in developing its own in-house sales force and sales plans.

137. Defendants' improper use and disclosure of AltaThera's confidential and proprietary information, including valuable trade secrets, allowed Defendants to enrich themselves at AltaThera's expense. Among other things, Defendants took information reflecting millions of dollars of investments by AltaThera and used that information as their own to identify and pursue a business opportunity in Dofetilide IV that they would not have pursued at all but for their improper use of AltaThera's confidential information—or, at a minimum, the improper use of such information gave them a head start that they would not have had but for that information.

138. Meanwhile, AltaThera has suffered and will continue to suffer substantial injury, including lost opportunities in connection with Dofetilide IV, loss of goodwill, and ultimately loss of market share in the market for intravenous antiarrhythmic agents, due to Defendants' misconduct.

139. AltaThera's business has already been negatively impacted by Defendants' misappropriation and misuse of AltaThera's trade secrets and confidential information. [redacted]

140. Additionally, Hyloris was aware of ([redacted]) AltaThera's ownership of any intellectual property developed by Dr. Somberg and API in connection with their work for AltaThera—including the Dofetilide IV Patent Application—and Hyloris nonetheless sought and obtained an assignment of the Dofetilide IV Patent Application from Dr. Somberg and API, which purported to transfer AltaThera's intellectual property to Hyloris. Defendants' conduct in this regard has injured AltaThera by interfering with its right to own and freely exploit its intellectual property, without the cloud of uncertainty associated with an improper and ineffective assignment.

COUNT I

(Defend Trade Secrets Act, 18 U.S.C. § 1836 – All Defendants)

141. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

142. AltaThera's information and materials relating to AltaThera's Sotalol IV one-day method constitute, or constituted at the relevant time, trade secrets.

143. Specifically, AltaThera's trade secrets include(d), but are not limited to: (a) AltaThera's idea for its one-day method for administering Sotalol IV; (b) the contents of AltaThera's Sotalol IV Patent Application, both the first draft and the filed version; (c) AltaThera's plan for navigating the MIDD program to gain FDA approval of AltaThera's Sotalol IV one-day method of Sotalol IV administration, as well as its MIDD meeting package, other MIDD filings, and learnings from the MIDD program (collectively, the "MIDD Material"); and, (d) its market research and know-how relating to commercialization of antiarrhythmic agents (the "Market Research and Know-How").

144. Each of these trade secrets derives, or derived at the relevant time, independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who could obtain economic value from the disclosure or use of the information.

145. First, AltaThera's one-day dosing method was not available publicly, generally known, or otherwise readily ascertainable through proper means by the public, competitors, or others who could obtain economic value from its disclosure or use until December 24, 2019, when U.S. Patent No. 10,512,620 issued and was published.

146. The idea for AltaThera's Sotalol IV one-day method derived economic value from its confidentiality. Had competitors been aware of the idea, they could have begun to use the idea to, at a minimum, seek (1) their own patent protection for the idea, or application of the idea to competing products, (2) FDA approval of the idea for their use, including as applied to competing products, and (3) to commercialize the idea or application of the idea to competing products. Indeed, the value of AltaThera's one-day dosing idea has been significantly compromised by Defendants' use of the idea prior to December 24, 2019, to develop a competing product and begin regulatory and other processes necessary to bring that product to market. At a minimum, absent an injunction, AltaThera will be required to compete with Dofetilide IV far sooner than it would have had Defendants not begun their efforts relating to Dofetilide IV until December 24, 2019. And, in fact, AltaThera may have been the first to seek patent protection for a one-day dosing method for Dofetilide IV had Dr. Somberg and API not used AltaThera's confidential information to do so.

147. Second, the first draft of AltaThera's Sotalol IV Patent Application was never made public and was not ever generally known or readily ascertainable through proper means by the public, competitors, or others who could obtain economic value from its disclosure or use. This first draft was and is maintained within the company as a confidential draft. And the final draft of AltaThera's Sotalol IV Patent Application, U.S. Patent Application No. 16/103,815, did not become publicly available, was maintained as a confidential document, and was not generally known or readily ascertainable through proper means until it was published by the USPTO on December 24, 2019 when it issued as U.S. Patent No. 10,512,620.

148. Each of the first draft and the filed version of AltaThera's Sotalol IV Patent Application derived economic value from not being generally known or readily ascertainable

through proper means by those who could obtain economic value from their disclosure or use. For one thing, they contained the one-day dosing idea, which derived value from its confidentiality as described above. And because the drafts were confidential, competitors could not lawfully access them to use them to develop competing treatments or to copy their language in order to gain patent protection for competing products. Indeed, the confidential drafts lost a significant portion of their value when Dr. Somberg and API copied their contents into applications for patent protection for the competing Dofetilide IV product. And the idea for the one-day dosing method and the drafts of AltaThera's patent application have provided economic value to Defendants, who—through their relationships with AltaThera—acquired, used, and disclosed the idea for AltaThera's Sotalol IV one-day method and the patent application improperly.

149. Third, AltaThera has maintained, and continues to maintain, its MIDD Materials as confidential trade secrets. The MIDD Materials are not publicly available, generally known or readily ascertainable through proper means by the public, competitors, or others who could obtain economic value from their disclosure or use. The FDA is required to retain the confidentiality of its discussions with AltaThera and its agents regarding the MIDD Materials as well as any information submitted to the FDA in connection with the process.

150. The MIDD Materials derive value from their confidentiality, in part because they should have allowed AltaThera (or its partners) to move more quickly than competitors to obtain FDA approval and to bring products to market well-before competitors, in particular in the context of a one-day dosing method for a class III antiarrhythmic drug. Defendants' unlawful use of the MIDD Materials has meant that the MIDD Materials do not provide AltaThera the same competitive advantage they would absent this unlawful use.

151. Fourth, AltaThera has maintained, and continues to maintain, its Market Research and Know-How as a confidential trade secret and has disclosed it to other entities [redacted] only subject to stringent confidentiality obligations. This material is not publicly available, generally known or readily ascertainable through proper means by the public, competitors, or others who could obtain economic value from its disclosure or use. This material derives value from its confidentiality, because it gives AltaThera a competitive advantage over competitors, and if disclosed, would, at a minimum, (1) inform potential competitors about the value of potentially competing drugs, incentivizing competitors to join the market, and (2) give competitors an ability to copy, undercut, or otherwise benefit from AltaThera's strategies.

152. AltaThera took reasonable measures to keep each of its trade secrets secret, including by entering confidentiality and non-use agreements with entities that could access them, as demonstrated by AltaThera's various agreements [redacted], each of which includes stringent confidentiality protections.

153. Each of AltaThera's trade secrets is related to a product (Sotalol IV) which was and is intended for use in interstate commerce.

154. Defendants used and disclosed, and continue to use and disclose, AltaThera's trade secrets, including by leveraging them to compete with AltaThera to develop, patent, and seek expedited FDA approval for a competing product and method (*i.e.*, Dofetilide IV) for commercialization in the United States.

155. Among other things, Dr. Somberg and API misappropriated AltaThera's trade secrets by (1) using AltaThera's one-day dosing method idea to develop the idea for the Dofetilide IV one-day dosing method; (2) copying AltaThera's patent applications, both the ideas they contained and the specific wording they used; (3) on information and belief, copying,

disclosing, and otherwise using AltaThera's MIDD Materials for use in seeking FDA approval for Dofetilide IV; and (4) using AltaThera's confidential Market Research and Know-How to make business decisions relating to Dofetilide IV, and (5) disclosing AltaThera's confidential information and trade secrets to Hyloris.

156. Among other things, Hyloris improperly misappropriated AltaThera's trade secrets by (1) using AltaThera's one-day dosing method idea to develop the idea for the Dofetilide IV one-day dosing method; (2) copying AltaThera's patent applications, both the ideas they contained and the specific wording they used; (3) on information and belief, copying, disclosing, and otherwise using AltaThera's MIDD Materials for use in seeking FDA approval for Dofetilide IV; and (4) using AltaThera's confidential Market Research and Know-How to make business decisions relating to Dofetilide IV, and (5) disclosing and using AltaThera's confidential Market Research and Know-How in the Hyloris IPO Prospectus.

157. As a result of Defendants' misappropriation of the trade secrets, Defendants have violated the DTSA, 18 U.S.C. § 1832 *et seq*.

158. As a direct and proximate result of Defendants' violation of the DTSA, AltaThera suffered compensatory and consequential damages and is entitled to those damages, as well as full attorneys' fees, costs, and expenses.

159. Defendants' actions in misappropriating AltaThera's confidential, proprietary, and trade secret information for their own gain was willful, wanton, and malicious, and taken with reckless disregard for the rights of AltaThera. AltaThera is thus entitled to exemplary damages of not more than twice the amount of damages for any actual loss and any unjust enrichment.

160. Defendants' actions have caused and will continue to cause AltaThera irreparable harm that is not adequately remedied at law and that requires preliminary and permanent injunctive relief preventing actual, continued, or threatened misappropriation of AltaThera's trade secrets.

COUNT II

(Illinois Trade Secrets Act, 765 ILCS 1065 – All Defendants)

161. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

162. AltaThera's information and materials relating to AltaThera's Sotalol IV one-day method constitute, or constituted at the relevant time, trade secrets.

163. Specifically, AltaThera's trade secrets include(d), but are not limited to: (a) AltaThera's idea for its one-day method for administering Sotalol IV; (b) the contents of AltaThera's Sotalol IV Patent Application, both the first draft and the filed version; (c) AltaThera's plan for navigating the MIDD program to gain FDA approval of AltaThera's one-day method of Sotalol IV administration, as well as its MIDD meeting package, other MIDD filings, and learnings from the MIDD program (collectively, the "MIDD Material"); and, (d) its market research and know-how relating to commercialization of antiarrhythmic agents (the "Market Research and Know-How").

164. Each of these trade secrets derives, or derived at the relevant time, independent economic value, actual or potential, from being sufficiently secret and not being generally known to, and not being readily ascertainable through proper means by, another person who could obtain economic value from the disclosure or use of the information.

165. First, the idea for the one-day dosing method was sufficiently secret and not available publicly, generally known, or otherwise readily ascertainable through proper means by the public, competitors, or others who could obtain economic value from its disclosure or use until, at the earliest, December 24, 2019, when U.S. Patent No. 10,512,620 issued and was published.

166. The idea for AltaThera's Sotalol IV one-day method derived economic value from its confidentiality. Had competitors been aware of the idea, they could have begun to use the idea to, at a minimum, seek (1) their own patent protection for the idea, or application of the idea to competing products, (2) FDA approval of the idea for their use, including as applied to competing products, and (3) to commercialize the idea or application of the idea to competing products. Indeed, the value of AltaThera's one-day dosing idea has been significantly compromised by Defendants' use of the idea prior to December 24, 2019, to develop a competing product and begin regulatory and other processes necessary to bring that product to market. At a minimum, absent an injunction, AltaThera will be required to compete with Dofetilide IV far sooner than it would have had Defendants not begun their efforts relating to Dofetilide IV until December 24, 2019. And, in fact, AltaThera may have been the first to seek patent protection for a one-day dosing method for Dofetilide IV had Dr. Somberg and API not used AltaThera's still-confidential information to do so.

167. Second, the first draft of AltaThera's Sotalol IV Patent Application was sufficiently secret, was never made public and was not ever generally known or readily ascertainable through proper means by the public, competitors, or others who could obtain economic value from its disclosure or use. This first draft was and is maintained within the company as a confidential draft. And the final draft of AltaThera's Sotalol IV Patent Application,

U.S. Patent Application No. 16/103,815, did not become publicly available, was maintained as a confidential document, and was not generally known or readily ascertainable through proper means until it was published by the USPTO on December 24, 2019 when it issued as U.S. Patent No. 10,512,620.

168. Each of the first draft and the filed version of AltaThera's Sotalol IV Patent Application derived economic value from not being generally known or readily ascertainable through proper means by those who could obtain economic value from their disclosure or use. For one thing, they contained the one-day dosing idea, which derived value from its confidentiality as described above. And because the drafts were confidential, competitors could not lawfully access them to use them to develop competing treatments or to copy their language in order to gain patent protection for competing products. Indeed, the confidential drafts lost a significant portion of their value when Dr. Somberg and API copied their contents into applications for patent protection for the competing Dofetilide IV product. And the idea for the one-day dosing method and the drafts of AltaThera's patent application have provided economic value to Defendants, who—through their relationships with AltaThera—acquired, used, and disclosed the idea for AltaThera's Sotalol IV one-day method and the patent application improperly.

169. Third, AltaThera has maintained, and continues to maintain, its MIDD Materials as confidential trade secrets. The MIDD Materials are sufficiently secret and not publicly available, generally known or readily ascertainable through proper means by the public, competitors, or others who could obtain economic value from their disclosure or use. The FDA is required to retain the confidentiality of its discussions with AltaThera and its agents regarding

the MIDD Materials as well as any information submitted to the FDA in connection with the process.

170. The MIDD Materials derive value from their confidentiality, in part because they should have allowed AltaThera (or its partners) to move more quickly than competitors to obtain FDA approval and to bring products to market well before competitors, in particular in the context of a one-day dosing method for a class III antiarrhythmic drug. Defendants' unlawful use of the MIDD Materials has meant that the MIDD Materials do not provide AltaThera the same competitive advantage they would absent this unlawful use.

171. Fourth, AltaThera has maintained, and continues to maintain, its Market Research and Know-How as a confidential trade secret and has disclosed it to other entities [redacted] only subject to stringent confidentiality obligations. This material is sufficiently secret and not publicly available, generally known or readily ascertainable through proper means by the public, competitors, or others who could obtain economic value from its disclosure or use. This material derives value from its confidentiality, because it gives AltaThera a competitive advantage over competitors, and if disclosed, would, at a minimum, (1) inform potential competitors about the value of potentially competing drugs, incentivizing competitors to join the market, and (2) give competitors an ability to copy, undercut, or otherwise benefit from AltaThera's strategies.

172. AltaThera took reasonable measures to keep each of its trade secrets secret, including by entering confidentiality and non-use agreements with entities that could access them, as demonstrated by AltaThera's various agreements [redacted], each of which includes stringent confidentiality protections.

173. Defendants used and disclosed, and continue to use and disclose, AltaThera's trade secrets in their businesses, including by leveraging them to compete with AltaThera to develop, patent, and seek expedited FDA approval for a competing product and method (*i.e.*, Dofetilide IV) for commercialization in the United States.

174. Among other things, Dr. Somberg and API misappropriated AltaThera's trade secrets by (1) using the one-day dosing method idea to develop the idea for the Dofetilide IV one-day dosing method; (2) copying AltaThera's patent applications, both the ideas they contained and the specific wording they used; (3) on information and belief, copying, disclosing, and otherwise using AltaThera's MIDD Materials for use in seeking FDA approval for Dofetilide IV; and (4) using AltaThera's confidential Market Research and Know-How to make business decisions relating to Dofetilide IV, and (5) disclosing AltaThera's confidential information and trade secrets to Hyloris.

175. Among other things, Hyloris misappropriated AltaThera's trade secrets by (1) using the one-day dosing method idea to develop the idea for the Dofetilide IV one-day dosing method; (2) copying AltaThera's patent applications, both the ideas they contained and the specific wording they used; (3) on information and belief, copying, disclosing, and otherwise using AltaThera's MIDD Materials for use in seeking FDA approval for Dofetilide IV; and (4) using AltaThera's confidential Market Research and Know-How to make business decisions relating to Dofetilide IV, and (5) disclosing and using AltaThera's confidential Market Research and Know-How in the Hyloris IPO Prospectus.

176. As a result of Defendants' misappropriation of the trade secrets, Defendants have violated the ITSA, 765 ILCS 1065 *et seq*.

177. As a direct and proximate result of Defendants' violation of the ITSA, AltaThera suffered compensatory and consequential damages and is entitled to those damages, as well as full attorneys' fees, costs, and expenses.

178. Defendants' actions in misappropriating AltaThera's confidential, proprietary, and trade secret information for their own gain was willful, wanton, and malicious, and taken with reckless disregard for the rights of AltaThera. AltaThera is thus entitled to exemplary damages of not more than twice the amount of damages for any actual loss and any unjust enrichment.

179. Defendants' actions have caused and will continue to cause AltaThera irreparable harm that is not adequately remedied at law and that requires preliminary and permanent injunctive relief preventing actual, continued, or threatened misappropriation of AltaThera's trade secrets.

COUNT III

(Breach of Contract – Dr. Somberg and API)

180. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

181. AltaThera and API entered into five valid agreements: the 2011 API Confidentiality Agreement, the 2016 API Confidentiality Agreement (the "API Confidentiality Agreements"), the January 2018 Consultant Agreement, the June 2018 Amended and Restated Consultant Agreement, and the August 2019 Second Amended and Restated Consultant Agreement (the "Consultant Agreements").

182. Dr. Somberg entered into two of these valid agreements: the API Confidentiality Agreements.

183. Dr. Somberg and API materially breached the API Confidentiality Agreements, and API materially breached the Consultant Agreements, by disclosing and using AltaThera's confidential information in ways barred by those agreements.

184. Among other things, Dr. Somberg and API materially breached the API Confidentiality Agreements, and API materially breached the Consultant Agreements, by using AltaThera's confidential information for their own business and commercial purposes, including, on information and belief, as a basis for the decision to seek patent protection and FDA approval relating to Dofetilide IV.

185. Dr. Somberg and API also materially breached the API Confidentiality Agreements, and API materially breached the Consultant Agreements, by copying AltaThera's confidential materials, including confidential draft and filed patent applications and, on information and belief, confidential regulatory materials, in order to pursue Dofetilide IV for their own purposes, and by filing copied materials with the USPTO and, on information and belief, the FDA.

186. Dr. Somberg and API also materially breached the API Confidentiality Agreements, and API materially breached the Consultant Agreements, by communicating AltaThera's confidential information, including information concerning the affairs, business, clients, customers or other relationships of AltaThera, to third parties, including Hyloris.

187. Dr. Somberg and API also materially breached the API Confidentiality Agreements by allowing Hyloris to use AltaThera's confidential information for its own business and commercial purposes relating to Dofetilide IV, and API breached the Consultant Agreements by failing to use reasonable efforts to prevent Hyloris's disclosures of AltaThera's confidential information.

188. On information and belief, Dr. Somberg and API materially breached the API Confidentiality Agreements by failing to return or destroy confidential material after their purpose had been accomplished or abandoned.

189. API also materially breached the Confidentiality Agreements by refusing to furnish AltaThera's documents which were in API's possession, and which were requested by AltaThera in connection with an FDA investigation, instead improperly withholding documents that already belonged to AltaThera and attempting to use them to extract from AltaThera a release of claims relating to Dofetilide IV.

190. Dr. Somberg's and API's breach of the agreements has caused damage to AltaThera. At a minimum, AltaThera lost the commercial advantage of maintaining the confidentiality of its ideas and plans, as well as the ability to use its own confidential and trade secret information to develop Dofetilide IV itself—free from competition from others with access to AltaThera's confidential information and trade secrets—and AltaThera now faces imminent competition from Dofetilide IV in the marketplace.

191. As the Consultant Agreements acknowledge, breach of the confidentiality provisions in those agreements has caused, and will continue to "cause irreparable harm to [AltaThera] not compensable in monetary damages" such that AltaThera is "entitled, in addition to all other applicable remedies, to a temporary and permanent injunction and a decree for specific performance … without being required to prove damages or furnish any bond or other security."

COUNT IV

(Breach of Contract – Hyloris)

192. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

193. The Hyloris License Agreement and [redacted] are valid [redacted] between AltaThera and Hyloris.

194. Hyloris materially breached [redacted].

195. Among other things, Hyloris materially breached [redacted] by [redacted], in the Hyloris IPO Prospectus.

196. Hyloris also materially breached the [redacted] by [redacted] relating to Dofetilide IV.

197. Hyloris also materially breached the [redacted] by [redacted] attempted to profit from that misuse.

198. As Hyloris agreed in the Hyloris License Agreement, there is [redacted] And, [redacted]

[redacted]

199. AltaThera has suffered and will continue to suffer damages as a direct result of Hyloris's breach of its [redacted]. At a minimum, AltaThera lost the commercial advantage of [redacted].

COUNT V

(Tortious Interference With Contract – Hyloris)

200. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

201. AltaThera entered into valid, enforceable contracts with API (the API Confidentiality Agreements and the Consultant Agreements), and with Dr. Somberg (the API Confidentiality Agreements).

202. On information and belief, Hyloris, by virtue of its relationships with AltaThera, API, and Dr. Somberg, was aware of the API Confidentiality Agreements and the Consultant Agreements.

203. Hyloris intentionally and unjustifiably induced API and Dr. Somberg to breach the API Confidentiality Agreements and the Consultant Agreements.

204. Among other things, Hyloris intentionally and unjustifiably induced API and Dr. Somberg to disclose and use AltaThera's confidential information, including draft patent applications and the MIDD Materials, to further Hyloris's efforts with respect to Dofetilide IV, in violation of the API Confidentiality Agreements and the Consultant Agreements.

205. For example, in April 2019, Hyloris agreed to reimburse API for development costs and pay API more than half a million dollars in exchange for, among other things, a license to the Dofetilide IV intellectual property that belonged to AltaThera under the Consultant Agreements. Shortly afterward, on June 24, 2019, Dr. Somberg and API filed the non-provisional Dofetilide IV Patent Application, copying verbatim large portions of the then-confidential application AltaThera filed relating to the Sotalol IV one-day method.

206. Dr. Somberg and API did breach the API Confidentiality Agreements and the Consultant Agreements as described in Count III, above. Dr. Somberg's and API's breaches—at a minimum including those occurring after the April 2019 execution of the binding term sheet between API and Hyloris—were caused by Hyloris's conduct.

207. As a result of Hyloris's tortious interference, AltaThera has suffered compensatory and consequential damages. At a minimum, AltaThera lost the commercial advantage of maintaining the confidentiality of its ideas and plans, as well as the ability to use its own confidential and trade-secret information to develop Dofetilide IV itself—free from competition from others with access to AltaThera's confidential information and trade secrets—and AltaThera now faces imminent competition from Dofetilide IV in the marketplace.

208. Further, as the Consultant Agreements acknowledge, breach of the confidentiality provisions in those agreements—which Hyloris induced—has caused, and will continue to "cause irreparable harm to [AltaThera] not compensable in monetary damages" such that AltaThera is "entitled, in addition to all other applicable remedies, to a temporary and permanent injunction and a decree for specific performance … without being required to prove damages or furnish any bond or other security."

COUNT VI

(Unjust Enrichment – All Defendants)

209. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

210. Hyloris, Dr. Somberg, and API unjustly retained benefits to AltaThera's detriment.

211. The Consultant Agreements provide that AltaThera is "the sole owner" of "all rights" to "results and proceeds" of API's services under the Consultant Agreements, including "any works of authorship resulting from or relating to [AltaThera's] business and/or [API's] services during [its] engagement" with AltaThera. At a minimum, the '796 application, and any patents that issue from that application (including the '213 patent), as well as any patents and patent applications that claim priority to that application (including the '413 application), constitute "results" and "proceeds" of API's services under the Consultant Agreements and resulted from or relate to AltaThera's business and/or API's services during its engagement with AltaThera.

212. AltaThera employee Mr. Kashfian is also a co-inventor of the inventions claimed in '213 patent, as he contributed to the conception of at least one of that patent's claims. Indeed, he conceived of the fundamental idea of AltaThera's one-day dosing method. That method is what made Dofetilide IV commercially viable.

213. But API and Dr. Somberg did not list Mr. Kashfian as an inventor on the '213 patent, and did not disclose the patent to AltaThera. Instead, API entered into a binding term sheet agreeing to license the patent exclusively to Hyloris in exchange for more than half a

million dollars, reimbursement of development costs, and an ongoing commercial relationship with Hyloris.

214. API's and Dr. Somberg's retention of those and other benefits violates the fundamental principles of justice, equity, and good conscience. The retention of those benefits is unjust, both under the Consultant Agreements and principles of equity.

215. For its part, Hyloris induced API and Dr. Somberg to breach their contractual and fiduciary obligations to AltaThera and executed a binding term sheet to license the '213 patent and other materials relating to Dofetilide IV which are a result of API's and Dr. Somberg's relationship with and work for AltaThera. Hyloris promotes Dofetilide IV as its product and raises capital based on its purported rights to Dofetilide IV, despite [redacted]. Further, Hyloris's misconduct will enable Hyloris to compete unfairly against AltaThera. It would be unjust, and a violation of the fundamental principles of justice, equity, and good conscience, for Hyloris's to retain such benefits.

COUNT VII

(Fraudulent Concealment – Dr. Somberg and API)

216. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

217. Dr. Somberg and API concealed their efforts to obtain patent protection and regulatory approvals relating to Dofetilide IV from AltaThera.

218. These efforts were material, because, pursuant to the Consultant Agreements, AltaThera owned "all rights" to "results and proceeds" of API's services under the Consultant

Agreements, including "any works of authorship resulting from or relating to [AltaThera's] business and/or [API's] services during [its] engagement" with AltaThera.

219. They were also material because AltaThera employee Mr. Kashfian was a rightful inventor of the '796 application, and patents that issue from that application (including the '213 patent), as well as patents and patent applications that claim priority to that application (including the '413 application).

220. API and Dr. Somberg were under a duty to disclose the fact of their efforts to obtain patent protection and regulatory approvals relating to Dofetilide IV to AltaThera. API and Dr. Somberg owed AltaThera a fiduciary duty, and, regardless, knew that AltaThera placed trust and confidence in them based on their experience and contractual relationship with AltaThera, placing API and AltaThera in a position of influence over AltaThera.

221. Further, Dr. Somberg and API owed a duty to AltaThera to disclose that they were seeking a patent for an innovation for which an AltaThera employee—Mr. Kashfian—was a true inventor.

222. AltaThera suffered damages as a result of API's and Dr. Somberg's fraudulent concealment. At a minimum, AltaThera was not able to have Mr. Kashfian recognized as an inventor on the '213 patent, and therefore unable to reap the benefits flowing from the patent based on Mr. Kashfian's assignment of his rights in the invention to AltaThera. Additionally, AltaThera has suffered and will continue to suffer harm from the competitive threat posed by Dofetilide IV.

COUNT VIII

(Breach of Fiduciary Duty – Dr. Somberg and API)

223. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

224. Dr. Somberg and API owed a fiduciary duty to AltaThera. At all relevant times, Dr. Somberg and API held a position of trust as AltaThera's consultant and advisor. AltaThera justifiably placed its trust in Dr. Somberg and API as a result of that long-standing relationship, and as a result of Dr. Somberg's experience and expertise regarding patents and medical, regulatory, clinical, and business affairs, such that Dr. Somberg and API gained superiority and influence over AltaThera. Additionally, Dr. Somberg and API acted as AltaThera's agent, including in connection with the regulatory approval process at the FDA.

225. Dr. Somberg and API accepted AltaThera's trust, then betrayed it and breached their fiduciary duties to AltaThera. They used their position of trust for their own purposes, and at AltaThera's expense, including by usurping AltaThera's business opportunities and naming Dr. Somberg as the sole inventor of AltaThera's discoveries. API and Dr. Somberg pursued Dofetilide IV, administered using a one-day method, for their own purposes, including by filing patent applications and obtaining the '213 patent listing Dr. Somberg as the exclusive inventor, and contracted with Hyloris in their own interest—and against AltaThera's best interest—when they should have been acting on AltaThera's behalf.

226. API's and Dr. Somberg's breach of their fiduciary duties was flagrant and intentional. They deliberately sought to usurp business opportunities that should have belonged to AltaThera for their own benefit and in an effort to bring a competing product to market. Indeed, Dr. Somberg and API delayed progress on AltaThera's efforts relating to Sotalol IV

while rushing to file patent applications relating to Dofetilide IV. Dr. Somberg and API deliberately failed to disclose their efforts relating to Dofetilide IV and agreement with Hyloris to AltaThera.

227. API's and Dr. Somberg's breach of their fiduciary duties proximately caused, and will continue to cause, injury to AltaThera. AltaThera lost the opportunity to exclusively develop Dofetilide IV using the one-day method itself, including any potential opportunity to license Dofetilide IV to another company, including to Hyloris. Instead, AltaThera lost its competitive advantage and will have to compete with Dofetilide IV, which will lead to lost profits and otherwise prevent AltaThera from realizing the value of its investments in the development of intravenous antiarrhythmic agents. AltaThera will suffer further irreparable injury for which it has no adequate remedy at law if API and Somberg are not enjoined. Because API's and Dr. Somberg's breach of their fiduciary duties was flagrant and intentional, AltaThera is also entitled to punitive damages.

COUNT IX

(Civil Conspiracy – All Defendants)

228. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

229. Defendants agreed to participate in an unlawful act or a lawful act in an unlawful manner. Hyloris, API, and Dr. Somberg agreed to participate in a scheme to use and disclose AltaThera's confidential and proprietary information in violation of [redacted] with AltaThera, to fraudulently conceal API's and Dr. Somberg's efforts to obtain patent protection and regulatory approvals relating to Dofetilide IV from AltaThera, and for Dr.

Somberg and API to breach their fiduciary duties to AltaThera by acting against AltaThera's interests and in their own, and Hyloris's, interests.

230. Indeed, Hyloris and API executed a binding term sheet agreeing that Hyloris will pay API to license Dofetilide IV, and Hyloris plans to distribute Dofetilide IV beginning in 2023, despite AltaThera's rightful ownership of the Dofetilide IV intellectual property Hyloris purports to license.

231. Defendants did perform tortious acts in furtherance of their common scheme, as described above.

232. Defendants' tortious acts caused AltaThera injury. AltaThera lost the opportunity to exclusively develop Dofetilide IV using the one-day method itself, including any potential opportunity to license Dofetilide IV to another company such as Hyloris. Instead, AltaThera lost its competitive advantage and will have to compete with Dofetilide IV, which will lead to lost profits and otherwise prevent AltaThera from realizing the value of its investments in the development of intravenous antiarrhythmic agents. AltaThera will suffer further irreparable injury for which it has no adequate remedy at law if API and Somberg are not enjoined. Defendants' conduct was wanton and willful, entitling AltaThera to punitive damages.

233. AltaThera therefore seeks judgment against Defendants jointly and severally for all damages, including without limitation and to the extent allowed by law, attorneys' fees and costs of suit, plus interest, and punitive damages.

COUNT X

(Correction of Inventorship Under 35 U.S.C. § 256(b) – All Defendants)

234. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

235. Mr. Kashfian made significant contributions to the conception of the subject matter claimed in the ’213 patent.

236. The invention claimed in the ’213 patent is the product of a collaboration between Mr. Kashfian and Dr. Somberg.

237. Mr. Kashfian is a joint inventor of the ’213 patent, but he was omitted as inventor on the patent.

238. Mr. Kashfian has assigned all right, title, and interest he has in the ’213 patent to AltaThera. As a rightful co-owner of the ’213 patent by virtue of this assignment, AltaThera has a substantial interest in ensuring that the identified inventorship of the patent is corrected so that AltaThera may freely practice, or license others to practice, the inventions claimed in the ’213 patent.

239. Section 256(b) of the Patent Act, 35 U.S.C., empowers a court in which the inventorship of a patent is called into question to order correction of the patent on notice and hearing of all parties concerned.

240. AltaThera is entitled to an order pursuant to § 256(b) correcting the inventorship of the ’213 patent to add Mr. Kashfian as a co-inventor.

COUNT XI

(Declaration of Ownership – All Defendants)

241. AltaThera re-alleges and incorporates by reference the allegations in all preceding paragraphs.

242. Pursuant to the Consulting Agreements, Dr. Somberg and API assigned ownership in the “results and proceeds” of API’s services under the Consultant Agreements, including any intellectual property (such as patentable inventions), to AltaThera.

243. The inventions described and claimed in the ’796 application, and any patents that issue from that application (including the ’213 patent), as well as any patents and patent applications that claim priority to that application (including the ’413 application), constitute “results and proceeds” under the Consultant Agreements, including because they were developed in the course of Dr. Somberg and API’s work for AltaThera, using AltaThera’s resources (including its intellectual property). Indeed, Dr. Somberg executed a formal, recordable assignment agreement in connection with the Sotalol IV Patent Application—which contains substantially overlapping disclosures of overlapping inventions, and which Dr. Somberg copied to produce the ’796 application—reflecting the already-operative assignment of rights to intellectual property contemplated by his the terms of his Consulting Agreements.

244. Dr. Somberg purported to assign the ’796 application, and any patents that issue from that application (including the ’213 patent), as well as any patents and patent applications that claim priority to that application (including the ’413 application), to API, and API purported to do the same to Hyloris. In each case, however, the purported assignment was made by an entity with actual notice of AltaThera’s ownership of the intellectual property.

245. AltaThera is the owner of the ’796 application, and any patents that issue from that application (including the ’213 patent), as well as any patents and patent applications that claim priority to that application (including the ’413 application), by virtue of the Consulting Agreements.

246. Pursuant to 28 U.S.C. §§ 2201 and 2202, AltaThera is entitled to a judicial declaration that it is the owner of the ’796 application, and any patents that issue from that application (including the ’213 patent), as well as any patents and patent applications that claim priority to that application (including the ’413 application).

JURY DEMAND

247. Pursuant to Federal Rule of Civil Procedure 38(b), AltaThera demands a jury trial.

PRAYER FOR RELIEF

WHEREFORE, AltaThera respectfully requests the following relief:

A. Compensatory and consequential damages;

B. Lost profits and exemplary and consequential damages, including but not limited to double damages for any actual loss to AltaThera cause by Defendants' misappropriation of trade secrets under the DTSA and Illinois law;

C. Disgorgement of Defendants' ill-gotten profits;

D. Preliminary and permanent injunctive relief, including but not limited to an injunction against Defendants' further use, disclosure, or dissemination of AltaThera's confidential information and/or trade secrets and the fruits thereof, including but not limited to any regulatory, marketing, or strategy materials incorporating or derived from AltaThera's confidential information and/or trade secrets;

E. An Order correcting the inventorship of the '213 patent pursuant to 35 U.S.C. § 256(b);

F. A declaration that AltaThera owns all right, title, and interest in the '796 application, and any patents that issue from that application (including the '213 patent), as well as any patents and patent applications that claim priority to that application (including the '413 application);

G. Attorneys' fees;

H. Pre-judgment and post-judgment interest;

I. Cost of suit; and

J. All other relief the Court deems appropriate.

Date: August 30, 2022

Respectfully submitted,

By: */s/ Steven J. Horowitz*

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